UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.usplo.gov

APPLICATION NO.	FILING DATE	. FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,303	12/02/2005	Colin Dunlop	GRIHAC P44AUS	3549
			EXAMINER	
112 PLEASANT S CONCORD, NH 0			PAPAPIETRO, JACQUELINE M	
			ART UNIT	PAPER NUMBER
			3739	
			MAIL DATE	DELIVERY MODE
		•	07/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-16, 18-19, 21, 27, 30-34, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Berke (US 5165400).

Regarding claim 15, Berke discloses a surgical warming blanket (10) comprising at least two layers (see Fig 5) capable of forming hollow air space between the two layers (hollow legs 13 and 14, Fig 1) for receiving warmed air from a heating unit (11), the two layers and air space being arranged in operation to form a substantially tubular arrangement at least partially surrounding a patient receiving space (see Fig 1), whereby when warm air is passes into the air space the warm air is delivered to the patient receiving space via the blanket (column 2 lines 34-40), to maintain warm air within the patient receiving space, the patient receiving space being arranged to receive the patient's body and allowing access to the patient's body for surgery without disturbing the blanket (as is clearly shown in Fig 1), and wherein one of the two layers of the blanket has a portion of its surface formed of pervious material so that the warmed air is delivered to the patient receiving space via the pervious material (column 3 lines 30-34, and lines 61-68). The term pervious has not been specifically defined in

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the specification; therefore, it has been given is broadest reasonable meaning, which includes the materials disclosed by Berke.

Regarding claims 16, 18-19, 21 and 30, Berke discloses the surgical warming blanket of claim 15, wherein the tubular arrangement surrounds the patient receiving space on three sides (see Figs 1 and 2), wherein the surface of the blanket is arranged to be fluid repellent (column 3 line 33-34), and wherein the surgical warming blanket is sized and shaped so that the patient receiving space is arranged to receive a human (see Fig 1) and is also capable of receiving an animal (such as a large dog or a monkey), and a small animal (small being a relative term and including a monkey or small cow) whereby to maintain warmth of the human or animal.

Regarding claims 27, 31-34 and 36, Berke discloses a method of warming a patient comprising the steps of receiving the patient within a patient receiving space within which the patient's body is accessible for surgery, and passing warmed air into a patient receiving space to keep the patient warm utilizing the surgical warming blanket as described above (see the abstract, column 1 lines 15-24, and column 2 lines 10-11).

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 22-26 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berke in view of Hagopian (US 4963997).

Berke discloses a heating unit (11) for the patient warming system described above, the heating unit including a delivery port (opening 16, Fig 3) for delivering warmed air to the patient warming blanket, described above, and a safety monitoring means for automatic shut-off (column 3 lines 6-8); the heating unit being arranged to heat the air to a range of temperatures, including up to 46 degrees C (column 3 lines 3-6). Berke does not disclose a pressure sensor feedback system.

Hagopian teaches an inflatable patient support system (Fig 1) with a control unit (10), pumps (22 and 24) and ports (88 and 90) for delivering air to the device and a feedback means for determining whether a patient warming blanket is attached; wherein the feedback means includes a pressure sensor for sensing back pressure on the air delivery port (column 4 line 65- column 5 line 17). Furthermore, pressure feedback systems are well known in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Berke by adding the pressure sensor feedback system as taught by Hagopian to the automatic

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shut-off safety mechanism in order to appropriately inflate the patient warming blanket to desired values when the blanket is attached.

Claims 29 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berke in view of Tomic-Edgar et al (US 6277144 B1).

Berke discloses the surgical warming blanket of claim 15 and the method of claim 27, as described above, but does not disclose a blanket base for the patient to lie on. Tomic-Edgar et al teaches an inflatable patient warming apparatus similar to the Berke apparatus (see Fig 1A), wherein a continuation of one of the layers provides a blanket base within the patient receiving space, arranged for the patient to lie on (column 4 lines 8-19). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Berke by adding the blanket base, as taught by Tomic-Edgar in order to add structural stability to the apparatus.

## Response to Arguments

Applicant's arguments filed 9 April 2007 have been fully considered but they are not persuasive.

Regarding Applicant's argument that the Berke device is impervious, Applicant is directed to column 3 lines 30-31 where Berke discloses, "suitable materials used in construction of the article include woven and non-woven fabrics." A woven fabric is pervious. Applicant asserts that air holes must be punched into the material of Berke in order to provide airflow. Berke does not support this assertion. Airflow would occur

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through a woven fabric without punching air holes in it. Furthermore, Applicant does not sufficiently define what a "pervious material" is. By punching holes a plastic, it becomes a pervious, or porous material. Applicant only discloses that "relatively high velocity streams of air" are not formed when air is delivered through a pervious/porous material. However, "relatively high" is an indefinite term. Therefore, "pervious material" must be given its broadest reasonable meaning. The Examiner takes the position that both the woven material and the plastic material with holes punched in it, disclosed by Berke, are pervious materials.

Regarding Applicant's argument that Berke does not disclose or suggest using the article during surgery, Examiner directs Applicant to column 1 lines 16-24. Berke discloses that hypothermia is caused by "cold operating room temperatures, breathing of dry anesthetic gases, adverse effects of anesthesia on body heat production and inhibition of temperature regulation, evaporation of moisture from exposed organs during the operation, and cold intravenous fluids." This clearly implies that the device should be used during the surgery.

Applicant's arguments with respect to claims 22-26 have been considered but are moot in view of the new ground(s) of rejection.

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Papapietro whose telephone number is (571) 272-1546. The examiner can normally be reached on M-F 9am-5:30pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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